KILGORE & KILGORE, PLLC
By: Robert E. Goodman, Jr.
Kilgore Law Center
3109 Carlisle Street
Dallas, Texas 75204
(214) 969-9099
Email: reg@kilgorelaw.com
Texas Bar ID 08158100; SD Texas Bar ID278353

BEGELMAN & ORLOW, P.C.
By: Marc M. Orlow, *admitted Pro Hac Vice*
Ross Begelman, *admitted Pro Hac Vice*
411 Route 70 East, Suite 245
Cherry Hill, New Jersey 08034
(856) 428-6020
Email: marc.orlow@begelmanorlow.com
ross.begelman@begelmanorlow.com
Attorneys for Relator

UNITED STATES, and the State of Texas, ex rel. Tina Strawn, Plaintiffs;	:	U.S. District Court for the Southern District of Texas
vs.	:	PURSUANT TO 31 U.S.C. 3729 et seq.
HARRIS HEALTH SYSTEM, 2525 Holly Hall, PO Box 66769 Houston, Texas 77054 Defendant	:	C.A. No.20-CV-00296

PLAINTIFF EX REL. STRAWN'S FIRST AMENDED COMPLAINT PURSUANT TO THE FALSE CLAIMS ACT, 31 U.S.C. §3729 et seq.

I. INTRODUCTION

Plaintiff/Relator Tina R. Strawn hereby files this Amended Complaint[1] pursuant to Section 31 U.S.C. §§ 3729 et seq., (the "FCA") for violations of 31 U.S.C. § 3729 regarding false claims on behalf of the United States Government.

1 . Ms. Strawn's action seeks to recover damages and civil penalties on behalf of the United States arising from false and/or fraudulent records, statements and claims made, used and caused to be made, used or presented by Defendant Harris Health System (hereafter referred to as "Defendant" or "HHS") and/or its agents, employees, under the False Claims Act.

2. Defendant HHS (a political subdivision of Harris County) is the largest integrated healthcare system that cares for all residents of Harris County, Texas.

3 . HHS operates two acute care hospitals and a hospital-based skilled nursing (until 2018) and rehabilitation facility (until 2018) and

[1] The original Complaint was filed on January 27, 2020 under seal pursuant to the provisions of the False Claims Act. On February 4, 2020, with the United States having declined to intervene in this action, the Court ordered the Complaint unsealed on February 4, 2020

psychiatric unit, with a total of at least 700 licensed beds. HHS also operates 18 primary care health clinics; 5 specialty clinics providing dental, dialysis, HIV/AIDS treatment and outpatient specialty services; 5 school-based clinics, 5 same day clinics, and 5 mobile health clinics.

4. HHS is exempt from federal income taxes.

5. Since at least March, 2010, Defendant has engaged in several illegal schemes by engaging in the following illegal and fraudulent activities:

(a) Submitting fraudulent claims for drugs intended for use in the various patient medical assistance bulk drug replacement programs. These drugs are received, from various manufacturers, at no cost, for use by its non-indigent population. Thereafter, Defendant diverts these drugs to patients other than those intended for whom the drugs were provided, and submits claims for reimbursement for the "free" drugs.

(b) Fraudulent use of the 340(b) program;

(c) Submitting charges for immunizations that were and are double billed, both for the drug itself and the administration; and

(d) Submitting fraudulent claims for newborn hospital stays at a higher level of care than was actually provided.

6. Defendant's conduct and schemes have cheated the Federal government out of millions of dollars that should not have been paid.

7. Relator Strawn is an original source of the allegations and transactions described in this Disclosure Statement, and the allegations and transactions described herein are not based upon publicly disclosed information.

II. THE PARTIES

A. Relator Tina Strawn

8. Tina Strawn is a registered nurse, and head of Patient Financial Services at Harris Health System. Ms. Strawn has held that position for nine years, with progressively increasing responsibility in the management of health care organizations, including but not limited to healthcare financial systems.

9 . For the first seven years of her career, Ms. Strawn worked as a bedside nurse at University of Texas Medical Branch, in Galveston, Texas. She then moved into utilization review and nurse auditing.

10. In 2008, Ms. Strawn joined HHS in Patient Financial Services. From 2008 to 2010, she served as Director of Revenue Cycle Management-Charge Capture. From 2010 to 2017, she served as Director of Revenue Cycle Management-Patient Financial Services. Most recently, Ms.

Strawn has served as Administrative Director of Operations, Patient Financial Services, from 2018 to present.

12. In these roles, Ms. Strawn manages over 150 employees, overseeing all financial issues at three hospitals (encompassing over 700 beds at Levels I and II trauma), eighteen primary care clinics, three multispecialty clinics, six same-day clinics, and five specialty clinics.

12. These jobs have provided Ms. Strawn with insight into how HHS manages its patient financial systems, including Medicare, Medicaid, private insurers, patients whose care is paid by grants, and indigent care.

13. Ms. Strawn also manages the Pharmacy Business Office, which includes the Drug Replacement and Assistance Program, prescription authorization, and pharmacy charge capture.

B. Harris Health Systems

a. Formation of Harris Health Systems

14. HHS was originally created as a political subdivision of the State of Texas by voter referendum in November 1965 as the Harris County Hospital District.[2]

15. At its creation, HHS was formally designated as a political subdivision with taxing authority on January 1, 1966. HHS is now a component unit of Harris County, Texas, but is a legally separate entity.

16. HHS' purpose is to provide medical care to the needy residents of a particular county. Tex. Const. art. IX, § 4; Tex. Health & Safety Code Ann. §§ 281.002, 282.049. The members of HHS's governing board are appointed by the Harris County Commissioners' Court. The Harris County Commissioners' Court approves HHS' tax rate and annual operating and capital budget.

17. Harris County, Texas does not provide any funding to HHS, hold title to any of HHS' assets, or have any rights to any surpluses of the System.

---

[2] A hospital district is a governmental entity in Texas, established pursuant to the Texas Constitution Tex. Const. art. IX, § 4; and the Tex. Health & Safety Code § 281.002[3], the purpose of which is to provide medical care to the needy residents of a particular county. § 281.002 [4]

18. HHS provides patient care to the indigent population of Harris County and receives property taxes levied by Harris County for the provision of this care. In January 2012, the Board of Trustees[3] of Harris County Hospital District approved a change of name to Harris Health System, which became effective on September 6, 2012.

19. HHS operates two acute care hospitals and a hospital-based skilled nursing and rehabilitation facility and psychiatric unit, with a total of 700 licensed beds.

20. HHS also operates 18 primary care health clinics; 5 specialty clinics providing dental, dialysis, HIV/AIDS treatment and outpatient specialty services; 5 school-based clinics, 5 same day clinics, and 5 mobile health clinics.

21. Michael Norby ("Norby") is the Executive Vice President and chief financial officer (Michael.Norby@harrishealth.org) of HHS. Dr. Michael Naddi ("Naddi") is the chief pharmacy officer. Pharmacy inventory was, until August, 2019, managed by Dr. Erika Brown ("Brown").

[3] Pursuant to the Tex. Health and Safety Code, the governing Board of Trustees comprises nine members appointed by Harris County Commissioners' Court. Each member serves a term of two years.

b. HHS Hospitals

22. Ben Taub Hospital, located at the Texas Medical Center, 1504 Taub Loop, Houston, Texas 77030, is one of HHS' acute care facilities and is a Level I trauma center. Ben Taub contains 444 licensed beds, and has more than 80,000 emergency patients visits each year.

23. Staffed by physician faculty and residents from Baylor College of Medicine and M.D. Anderson Cancer Center, Ben Taub Hospital also serves as a teaching facility. In addition to trauma, stroke, emergency and acute care services, Ben Taub provides outpatient clinical care in a wide array of medical specialties.

24. Lyndon B. Johnson Hospital ("LBJ"), is located at 5656 Kelley Street Houston, Texas 77026. LBJ is a 207 licensed-bed acute care hospital offering a full range of medical services and a verified Level III trauma center. It has more than 70,000 emergency patient visits each year. Physician faculty and residents with The University of Texas Health Science Center at Houston and M.D. Anderson Cancer Center oversee the provision of medical care to patients at LBJ Hospital.

c. Primary Care Locations

25. Through its nineteen (19) community health centers (12 of which have pharmacies), and four (4) school-based clinics (none of which have pharmacies), HHS provides more than 900,000 primary care doctor visits and over 1.7 million total outpatient visits each year.

26. HHS is the largest public primary care health network in the state of Texas. The health system offers patients access to doctors from Baylor College of Medicine, McGovern Medical School at The University of Texas Health Science Center at Houston, and M.D. Anderson Cancer Center. A summary of these locations, both Community-based and school-based, is set forth below.

d. Community Based Centers

27. Thomas Street Health Center [Community-based, including a pharmacy]. Thomas Street Health Center is a freestanding HIV/AIDS clinic located at 2015 Thomas Street, Houston, Texas 77009. Thomas Street provides medical and specialty care, and psychological and social services, to those who have been diagnosed with HIV/AIDS. Thomas Street also has on-site pharmacy services.

28. Vallbona Health Center [Community-based, including a pharmacy]. Vallbona Health Center provides medical and specialty care to adults and children living in southwest Houston located at 6630 DeMoss Street, Houston, Texas 77074-5004. The center also provides on-site laboratory, pharmacy and x-ray services.

29. Acres Home Health Center. [Community-based, including a pharmacy]. Acres Home Health Center provides medical and specialty care services to both adults and children in the north and northwest neighborhoods of Houston at 818 Ringold Street, Houston, Texas 77088. The center provides on-site laboratory, pharmacy and x-ray services.

30. Cypress Health Center [Community-based, with no pharmacy]. Cypress Health Center provides primary and specialty care services to both adults and children in the north and northwest neighborhoods of Houston at 12340 Jones Road, Suite 100 Houston, Texas, 77070.

31. Danny Jackson Health Center [Community-based, with no pharmacy]. Danny Jackson Health Center provides primary and specialty care services to both adults and children. 5503 N. Fry Road, Katy, Texas 77449.

32. Aldine Health Center [Community-based, including a pharmacy]. Aldine Health Center provides medical and specialty care services to adults and children living in the Aldine and far-north Houston community at 755 Aldine Mail Route, Houston, Texas 77039-5934. The center also has on-site laboratory, pharmacy and x-ray services.

33. Baytown Health Center [Community-based, including a pharmacy]. Baytown Health Center provides medical and specialty care to adults and children living in the Baytown area at 1602 Garth Road, Baytown, Texas 77520-2410. The center has on-site laboratory and pharmacy services.

34. Casa De Amigos Health Center [Community-based, including a pharmacy]. Casa de Amigos Health Center offers primary and specialty medical care to adults and children residing in the central and near-north area of Houston at 1615 North Main Street, Houston, Texas 77009. The center also provides on-site laboratory and pharmacy services.

35. El Franco Lee Health Center [Community-based, including a pharmacy]. El Franco Lee Health Center provides primary and specialty healthcare services to adult and pediatric residents of southwest-Houston

at 8901 Boone Road, Houston, Texas 77099. The Center also provides onsite pharmacy services.

36. Gulfgate Health Center [Community-based, including a pharmacy]. Gulfgate Health Center provides primary and specialty healthcare services to adult and pediatric residents in the central-southeast area of Houston at 7550 Office City Drive, Houston, Texas 77012. The center also provides on-site pharmacy, laboratory and x-ray services.

37. Martin Luther King Jr. Health Center [Community-based, including a pharmacy]. Martin Luther King Jr. Health Center provides medical and specialty healthcare services to both adults and children in southeast Houston located at 3550 Swingle Road, Houston, Texas 77047. The center also provides on-site pharmacy, laboratory, and x-ray services.

38. Northwest Health Center [Community-based, including a pharmacy]. Northwest Health Center provides adult and pediatric medical and specialty healthcare services to residents in northwest Houston at 1100 West 34th Street, Houston, Texas 77018. The center also provides on-site laboratory, pharmacy and nutrition services.

39. Pediatric & Adolescent Health Center–Bear Creek [Community-based, but no pharmacy]. Pediatric & Adolescent Health Center–Bear Creek provides primary and specialty healthcare for newborns to teens up to 18 years of age. It is located at 5870 Highway 6, Suite 108, Houston, TX 77084.

40. Pediatric & Adolescent Health Center–C.E. Odom [Community-based but no pharmacy]. Pediatric & Adolescent Health Center–C.E. Odom provides primary and specialty healthcare services for newborns to teens up to 18 years of age. It is located at 5516 Lockwood, Houston, Texas 77026.

41. Pediatric & Adolescent Health Center [Community-based, but no pharmacy] - Pasadena Pediatric and Adolescent Health Center–Pasadena, provides primary and specialty healthcare for newborns to teens up to 18 years of age. The center is located at 3925 Fairmont Parkway Pasadena, Texas 77504.

42. Settegast Health Center [Community-based, but no pharmacy]. Settegast Health Center provides primary and specialty healthcare

services to adults and children in far-northeast Houston at 9105 North Wayside Drive, Houston, Texas 77028.

43. Southside Health Clinic [Community-based, but no pharmacy]. Southside Health Clinic offers primary and specialty healthcare services to children and adolescents in the Galena Park area at 1721 16th Street, Galena Park, Texas, 77547.

44. Squatty Lyons Health Center [Community-based, including a pharmacy]. Squatty Lyons Health Center provides primary and specialty healthcare services to adults and pediatrics at 1712 First Street E, Suite M20, Humble, Texas 77338-5238. The center also provides on-site counseling and pharmacy services.

45. Strawberry Health Center [Community-based, including a pharmacy]. Strawberry Health Center provides primary and specialty healthcare services to adults and children at 927 Shaw Ave., Pasadena, Texas 77506-1430. The center also provides on-site pharmacy and laboratory services.

e. School Based Clinics [No Pharmacies]

46. A.C. Taylor Health Clinic. Almatha Clark Taylor Health Clinic offers preventive and acute healthcare services, including immunizations, to children and adolescents in the east Houston area located at Cloverleaf Elementary (Galena Park ISD), 13940 Bonham Street Houston, Texas 77015.

47. Goose Creek Health Clinic. Goose Creek Health Clinic offers preventive and acute healthcare services, including immunizations, to children and adolescents in the Baytown area. The Goose Creek Health Clinic is located at San Jacinto Elementary (Goose Creek CISD), 706 Kentucky Street, Baytown, Texas 77520.

48. Robert Carrasco Health Clinic. Robert Carrasco Health Clinic offers preventive and acute healthcare services, including immunizations, to children and adolescents in north-central Houston at Marshall Middle School (Houston ISD), 1115 1/2 Noble, Houston, Texas 77009.

49. Sheldon Health Clinic. Sheldon Health Clinic offers preventive and acute healthcare services, including immunizations, to children and adolescents in the Sheldon/Channel view area and is located at Sheldon

Elementary (Sheldon ISD), 17203 1/2 Hall Sheppard, Houston, Texas 77049.

f. HHS Captive HMOs

50. Community Health Choice, Inc. ("CHC") and Community Health Choice Texas, Inc. ("CHCT") (the HMOs) are Texas not-for-profit corporations organized under Section 501(c)(4) of the Internal Revenue Code to operate as health maintenance organizations (HMOs).

51. The HMOs are reported as discretely presented component units of HHS, since the HMOs' Board of Directors are appointed by the HHS' Board of Trustees and the HHS can impose its will on the HMOs.[4]

52. CHC is a local, non-profit managed care organization (MCO) licensed by the Texas Department of Insurance. It is affiliated with the Harris Health System, but does not receive any tax support. CHC was

[4] Under Government Accounting Standard Board (GASB) Number 14, HHS is required to financially report and disclose for the organizations that make up its legal entity. It is also financially accountable for legally separate organizations if its officials appoint a voting majority of an organization's governing body and either it is able to impose its will on that organization or there is a potential for the organization to provide specific financial burdens on, the primary government. A primary government may also be financially accountable for governmental organizations that are fiscally dependent on it.

incorporated on May 8, 1996, licensed by the Texas Department of Insurance on February 14, 1997,

53. As of December 31, 2016, CHC offered three Medicaid insurance products, as well as individual health insurance on the Health Insurance Marketplace, for 358,601 enrollees.

54. Community Health Choice Texas, Inc. ("CHCT") was formed in August, 2016 to allow the Health Insurance Marketplace and the Medicaid insurance products to be provided and served by separate corporations.

55. There are two parts of CHCT. CHCI is the Health Insurance Marketplace and commercial HMO with 140,210 enrollees as of December 31, 2017. CHCT is the Medicaid Managed Care HMO with 285,294 enrollees as of December 31, 2017.

56. In December 2017, HHS contributed $60 million to CHC to provide additional risk-based capital for the calendar year ending December 31, 2017.

57. The HMOs (Community Health Choice Texas, Inc., the Medicaid Managed Care HMO, and Community Health Choice, Inc., the Health Insurance Marketplace and commercial HMO) experienced a 17.8 percent growth in membership during fiscal 2018 and 21.7 percent growth in membership during fiscal 2017.

58. Revenue obtained related to HMO premiums is recognized as revenue by the HMOs during the coverage period of the subscriber agreement. For the primary Medicaid business, notification is received throughout the year of any new, removed, or revised members and the date of eligibility for coverage. The date of notification may be subsequent to the date of eligibility.

g. HHS Revenue Sources

59. HHS obtains its income through various sources, including Medicare, Medicaid, and self-pay patients.

60. HHS has a financial assistance program for uninsured patients classified as self-pay. This program determines the patient's expected payments for services rendered based upon the Medicare allowable

reimbursement. Charges in excess of the patient's expected payment are reflected as an "administrative uninsured discount."

61. HHS' allowance in its revenue for uncollectible accounts, mostly due to the large number of uninsured patients it treats, was estimated at $85.1 million in February, 2018, and $94.2 million as of February, 2017.

62. HHS provides services to patients covered under the Medicare and Medicaid programs, through its own contracts with Medicare and Medicaid. HHS' net revenues from these programs are included in its patient service revenue.

63. These revenues are determined from an estimated Medicare or Medicaid reimbursement, based on customary billing charges. These customary charges reflect predetermined rates of reimbursement, plus certain adjustments. The amounts due to, or from, these programs are subject to final review and settlement by the Medicare and/or Medicaid program fiscal intermediaries.

64. Retroactive adjustments to its reimbursement, under third-party reimbursement agreements, are reflected in HHS' annual recognition of revenue on an estimated basis, in the period the related services are

rendered. Such amounts are adjusted in future periods as adjustments become known.

65. Medicare Inpatient acute care services and defined capital costs related to Medicare program beneficiaries are paid at prospectively determined rates per discharge. These rates vary according to a patient classification system that is based on clinical diagnosis and other factors.

66. Medicare outpatient services are reimbursed on fee schedules and on a prospective basis through ambulatory payment classifications, which are based on clinical resources used in performing the procedures.

67. Medicare also permits HHS to claim on its cost reports amounts related to unreimbursed care. Since HHS provides significant amounts of unreimbursed care, these amounts are likely large.

68. Medicaid inpatient services rendered to Medicaid program beneficiaries are paid at prospectively determined rates per discharge, similar to those of the Medicare inpatient program.

69. Medicaid also provides a payment exception for the cost or day outlier payments for patients less than twenty-one years of age.

70. Medicaid outpatient services are paid by fee schedules for specific services provided, including outpatient surgery, imaging and laboratory services. Other outpatient services are reimbursed based on reasonable cost, based on a percentage calculated from HHS' most recent Medicaid cost report.

71. For years ending February 28, 2017 and February 28, 2018, revenue received from the Medicare program accounted for approximately 35 percent and 37 percent of HHS' total cash collections for net patient service revenue, respectively. For years ending February 28, 2017 and 2018, revenue received from the Medicaid program (including managed Medicaid) accounted for approximately 41 percent and 39 percent of HHS' total cash collections for net patient service revenue, respectively.

1- Medicaid Supplemental Programs

72. The Disproportionate Share III ("DSH") program, as part of the Medicare and Medicaid programs, was adopted in fiscal 1992 by the State of Texas to access additional federal matching funds. These funds are distributed to selected hospitals that provide services to low-income and uninsured patients, including but not limited to HHS.

73. The Upper Payment Limit ("UPL") program was created in May 2002 with an effective date of July 2001. The UPL program used federal matching funds to raise state Medicaid reimbursement rates to 100 percent of equivalent Medicare rates for certain public hospital systems, including but not limited to HHS.

a. Section 1115 Waiver

74. Section 1115 of the Social Security Act gives the Secretary of Health and Human Services authority to waive provisions of major health and welfare programs authorized under the Act, including certain Medicaid requirements, and to allow a state to use federal Medicaid funds in ways that are not otherwise allowed under federal rules. The authority is provided at the Secretary's discretion for demonstration projects that the Secretary determines promote Medicaid program objectives.

75. Section 1115 Medicaid waivers may allow changes in eligibility, benefits, cost sharing, and provider payments, or a more narrowly drawn focus on specific services and populations.

76. In December, 2011, Texas received CMS ("Center for Medicare/Medicaid Services") approval to redirect Texas Medicaid funding

it would have received under the UPL program for a five-year Section 1115 Waiver. It renewed from December, 2017, through September 30, 2022.

77. The 1115 Waiver program created two new pools of funding, the uncompensated care ("UC") pool and the delivery system reform incentive payment ("DSRIP") pool. The UC pool directs more funding to hospitals that serve large numbers of uninsured patients, such as HHS. The DSRIP pool provides incentive payments for healthcare providers based on improvements in quality of care.

78. As of February 28, 2018, HHS also participates in two other Medical Supplemental Payment Programs, the Network Access Improvement Program ("NAIP") and the new Uniform Hospital Rate Increase Program ("UHRIP").

79. HHS recognizes all funds received under the DSH, UC, DSRIP, NAIP and UHRIP programs as operating revenues in the period applicable to the funds.[5] Any amounts related to that year that are not

[5] Prior to 2017, HHS recognized funds received under the DSRIP program as nonoperating revenues.

received as of fiscal year- end are recorded as receivables and reflected in other current assets in the accompanying statements of net position. These receivables can be subject to adjustments that are reflected in the period they become known.

2- Charity Care Policy

80. Charity services are defined as those services for which no payment is anticipated. These amounts are not reported as revenue. HHS maintains records to identify and monitor the level of charity care it provides.

81. Charity care records include the amount of charges foregone for services and supplies furnished under HHS' Financial Assistance program.

82. HHS accepts all indigent Harris County residents as patients regardless of their ability to pay. The extent to which a resident would be financially responsible is determined based upon pre-established financial criteria, which utilize family income and size as it relates to the federal poverty guidelines set by the U.S. Department of Health and Human

Services. Harris County residents may also qualify for partial financial assistance on a sliding scale.

83. The following information measures the level of charity care provided during the years ended February 28, 2018 and 2017 (in thousands):

	2018	2017
Charges foregone, based on established rate:	$1,402,321	$1,524,954
Costs of foregone charges, estimated:	$651,623	$659,824

h. Key players in the HHS system

84. In addition to Norby, Naddi and Brown formerly the chief operations officer, terminated August, 2019, David Webb is the chief information officer' Anthony Williams is the compliance officer, Dr. Glorimar Medina-Rivera is the executive vice president and administrator of Ambulatory Care Services, and Terry Hoffman is the director of Ambulatory Pharmacy Services.

III. SUMMARY OF HHS' ILLEGAL CONDUCT

85. As detailed below, Defendant has engaged in several illegal schemes by engaging in the following illegal and fraudulent activities:

(a) diverting drugs to the inpatient setting which were intended for use in the various patient medical assistance bulk drug replacement programs. Thereafter, Defendant provides those drugs to patients with insurance, then submits claims for reimbursement for these drugs,

(b) fraudulent use of the 340(b) program, by diverting specific bulk replacement/patient assistance drugs to the inpatient setting, in order to avoid purchasing such drugs in the inpatient setting, where the drugs would be more expensive. These actions lower HHS' inpatient pharmacy costs while maximizing profits by purchasing the drugs in the outpatient setting, at a less expensive price, under the 340B program;

(c) making adjustments to HHS' billing and operating system, ("EPIC"), resulting in double and triple charging for immunizations, and then billing, via both professional claim forms Form 1500s and UB-04s, for two services that should only have been billed out as one service on one of the forms. These actions resulted in payors' processing systems being unable to identify errors, and paying twice for the same event. These

submissions resulted in double payments which would have been denied had the payors been aware of the double-billing.

(d) falsely submitting claims for inpatient care provided to newborns by making it appear that these patients require care at a higher level than was actually provided. These submissions resulted in the payment of cost outliers in situations where the patient would not have qualified had the appropriate room level been charged.

A. Bulk Replacement Patient Medical Assistance Programs

1. Background

86. The Federal Government has long recognized that Patient Assistance Programs ("PAPs") have provided an important safety net assistance to patients of limited means. In a Special Advisory Bulletin published in the Federal Register in 2005, it set out parameters for PAPs and its concerns related to the abuse and fraud in PAPs that would violate the Federal anti-kickback statute[6] and incur potential liability under the False Claims Act, 31 U.S.C. 3729–33, or other Federal or State laws.

87. PAPs are structured and operated in many different ways. PAPs may offer cash subsidies, free or reduced price drugs, or both. Some PAPs offer assistance directly to patients, while others replenish drugs furnished by pharmacies, clinics, hospitals, and other entities to eligible patients whose drugs are not covered by an insurance program.

88. "Bulk replacement" or similar programs are one type of PAP, pursuant to which pharmaceutical manufacturers (or their affiliated

[6] 70624 Federal Register/Vol. 70, No. 224/Tuesday, November 22, 2005, 42 CFR 423.782.

PAPs) provide in-kind donations in the form of free drugs to pharmacies, health centers, clinics, and other entities that dispense drugs to qualifying uninsured patients.

89. Bulk replacement model PAPs, also known as institutional PAPs ("IPAP"), allow health care facilities to obtain bulk quantities of medications for qualifying uninsured patients seen at their institutions rather than applying for each patient individually. See Special Advisory Bulletin: Patient Assistance Programs for Part D Enrollees, 70 F. R. 70623, 70628 (Nov. 22, 2005).

90. IPAPs, as contrasted with individual patient enrollment PAPs (that require hospitals to communicate each patient's eligibility information to the PAPs on a patient-by-patient basis), can represent a more efficient and practical means for health care providers to ensure that financially-needy patients get enrolled for PAP assistance, and get the medicines they need.

91. Whether a particular IPAP complies with the fraud and abuse laws requires a case-by-case analysis. In undertaking any analysis, the material factors to consider are how the program is structured and whether there are safeguards in place (i) to protect Federal health care

program beneficiaries from being steered to particular drugs based on the financial interests of their health care providers or suppliers; (ii) to protect the Federal health care programs from increased program costs; and (iii) to ensure that bulk replacement drugs are not improperly charged to Federal health care programs.

92. The central concern is whether the IPAP may be a vehicle through which the drug supplier offers or pays remuneration to participating hospitals either: (1) to induce the participating hospital to purchase or order (or arrange for, or recommend, the purchasing or ordering of) their products that are payable by a Federal health care program; or (2) to influence the prescribing patterns of physicians at participating hospitals with respect to the supplier's products that are payable by a Federal health care program.

93. Participating Hospitals such as HHS are in a position to generate Federal health care program business because they treat Federal health care program patients, purchase and dispense pharmaceutical products that may be payable by Federal health care programs, and have

physicians who prescribe pharmaceutical products that may be payable by Federal health care programs.

2. The Bulk Replacement Programs At Harris Health Systems

94. HHS operates over three hundred different PAPs throughout its system. Of these, approximately 43 are "bulk replacement," i.e., IPAPs.

95. For these IPAP Programs, HHS is required to have a bulk shipment agreement (IPAP Agreement) between the drug manufacturer and HHS, in order to cover the costs of medications outlined in the IPAP Agreement. (See four such agreements, attached as Exhibits 1, 2, 3, and 4).

96. Again, these programs are only for patients who qualify for the manufacturers' assistance program.

97. Set forth below is a summary of the bulk replacement or IPAPs at HHS.

Bulk Drug Replacement Chart

GENERIC NAME	BRAND NAME
Diclofenac/Misoprostol	Arthrotec
Mometasone	Asmanex
Moxifloxacin	Avelox

AmLodipine/Atorvastatin	Caduet
Celecoxib	Celebrex
Varencicline	Chantix
Desloratadine	Clarinex
Indinvair	Crixivan
Medroxyprogesterone	Depo-Provera
Tolterodine	Detrol
Tolterodine ER	Detrol LA
Phenytoin	Dilantin
Phenytoin	Dilantin Infatab
Extended Phenytoin	Dilantin Kap
Estrogen/Bazedoxifene	Duavee
Rilpivirine	Edurant
Piroxicam	Feldene
Miglitol	Glyset
Eplerenone	Inspra

Etravirine	Intelence
Canagliflozin	Invokamet
Canagliflozin	Invokana
Raltegravir	Isentress
Rizatriptan	Maxalt
Rifabutin	Mycobutin
Mometasone	Nasonex
Nicotine	Nicotrol
Nitroglycerin	Nitrostat
Conjugated estrogens	Premarin

	Premphase
	Prempro
Darunavir/Cobicistat	Prezcobix
Darunavir	Prezista
Desvenlafaxine	Pristiq
Nifedipine	Procardia XL
Albuterol	Proventil
Eletriptan	Relpax
Montelukast	Singulair
Metaxalone	Skelaxin
Fesoterodine fumarate ER	Toviaz
Dorzolomide	Trusopt
Sildenafil	Viagra

Ezetimibe	Zetia

98. HHS Department of Pharmacy ("DOP"), in collaboration with Patient Financial Services ("PFS–PMAP"), is responsible for investigating, implementing and utilizing all pharmacy medication assistance programs available to HHS patients to decrease the cost of overall pharmacy expenses.

99. PFS–PMAP is required to follow the respective guidelines in each IPAP Agreement with individual drug manufacturers, including submitting to the manufacturers the information required in each contract regarding qualified patients.

100. Under each IPAP Agreement, the DOP cannot submit claims for payment or reimbursement to any third party payors, including Government payors, for IPAP medications.

101. When applicable, the accounts of patients receiving medication through an IPAP shall be credited for the cost of the medication.

102. A Drug Replacement Program ("DRP") code is required to be used to identify patient prescriptions that have qualified ("Qualified Patients") for

an IPAP ("Program Drugs") to prevent third party billing. See Exhibit 5 DOP Departmental Guidelines and Procedures.

3. Drug Diversion in Harris IPAP Bulk Replacement Programs.

103. Neither the Bulk Replacement IPAPS nor the Inpatient/Outpatient Patient-Specific Replacement programs, as operated at HHS, have adequate safeguards to ensure that (a) that the replacement drugs are not improperly charged to Federal health care programs; (b) there is no inducement by HHS to purchase or order (or arrange for, or recommend, the purchasing or ordering of) the manufacturers' products that are payable by a Federal health care program; and (c) there is no potential for influence on the prescribing patterns of physicians at HHS with respect to a manufacturers products that are payable by a Federal health care program.

104. In order to prevent fraud, and safeguard the system, the IPAP program at HHS (and the DOP) is required, by most of its IPAP Agreements with manufacturers (See, e.g. Exhibit 1 through 4), to prevent HHS from obtaining excess stocks of drugs from which HHS could benefit.

105. HHS is getting one-for-one replacements (one replacement for one drug utilized on a qualifying patient), then diverting some of those bulk replaced drugs away from the prescription pharmacies that dispensed the original drug (to be provided to the qualifying patient).

106. The replacement drugs are improperly being sent to one of the inpatient pharmacies. This diversion is occurring in order to reduce the costs to the inpatient pharmaceutical budget.

107. For Inpatient/Outpatient Patient-Specific Replacement programs, there are two ways in which drugs are supplied.

108. The first manner relates to formulary drugs that have already been vetted through the Pharmacy and Therapeutics Committee. These drugs are readily available for ordering inside EPIC.

109. At the time of the drug order for already-vetted drugs, there are no medical necessity reviews to determine if this is the right drug for the patient, or reviews to see if there is a lower cost drug that could be used with equal effectiveness. Instead, Pharmacy's Inventory team makes the drug order available to the physician, and once ordered, PMAP begins the

process of assisting the patient to complete the application and getting the PAP approved.

110. The second manner for drug provision in patient-specific replacement relates to non-formulary drugs.

111. An order for these drugs can't be placed in EPIC until it has been reviewed and approved by the Inventory team. The Inventory team reviews order-by-order and case-by-case in order to validate medical necessity and/or to see if alternative drugs – more cost-effective drugs – could be utilized.

112. If the DOP Inventory team approves for the physician to order the drug (approval rate was 90%+ in 2017), HHS' Patient Financial Services ("PFS") calls the manufacturers, to see if a replacement/IPAP program is available.

113. If a patient-specific replacement is possible, PFS works with the patient and physician to have the application completed, submitted and approved.

114. Each drug is required to be used for the specific patient for whom it has been approved.

115. The DOP at HHS knowingly uses drugs provided as replacement drugs (for a particular patient) in a transfer of the drugs for use in HHS' inpatient/outpatient pharmacies.

116. Once transferred to another pharmacy—whether inpatient or outpatient--the drugs are utilized for patients other than the one specific patient for whom the drug was provided, without seeking, or receiving, permission from the manufacturer to utilize that drug on a different and potentially non-qualifying patient.

117. The rationale behind the bulk replacement diversion is to permit HHS to minimize the costs of drugs purchased for inpatients by using IPAP drugs in the inpatient setting.

118. The prescription (or outpatient) pharmacies, which are now missing stock of the IPAP drugs, are then required to purchase drugs which should have been received as replacement.

119. The outpatient purchase is made by using the outpatient pricing methodology, 340B, which is significantly less expensive than purchasing inpatient under the WAC ("Wholesale Acquisition Cost").

120. This scheme of transferring IPAP drugs to inpatient use, thus lowers the overall costs of the drugs to HHS.

121. Inpatient drugs are purchased at either WAC or AWP ("Average Wholesale Price"). WAC stands for wholesale acquisition costs, the list price from a manufacturer to a wholesaler or a direct purchaser without discounts. AWP stands for average wholesale price. AWP is the average price paid by a retailer to buy a drug from a wholesaler.

122. Outpatient drugs may be purchased at hospitals such as HHS, for use in their outpatient populations, under the 340B program, because HHS serves such a large quantity of indigent patients.

123. 340B pricing permits hospitals and health centers such as HHS to purchase drugs at a highly discounted rate, with a rate ceiling of (1) its Average Manufacturer Price ("AMP") for the smallest unit of measure (to six decimal places) minus (2) the Unit Rebate Amount ("URA"). 42 C.F.R.

§ 10.1, 10.2, 10.3, 10.10, and 10.11. The ceiling price is specific to each drug's 11-digit National Drug Code ("NDC").

124. Covered entities that participate in 340B are required to permit audits of records directly pertaining to compliance, and must maintain records that demonstrate compliance with all expected criteria for every prescription which results in a 340B drug being dispensed or accumulated through the covered entities' replenishment model.

125. HHS does not ensure that its overall utilization of a manufacturer's products is decoupled from participation in a replacement program. For every high dollar non-formulary request put in by the physicians, there is a request to see if a patient-specific replacement program is available.

126. Dr. Alyssa G. Rieber[7] and Dr. Martha Mims are the main physicians directly involved in clinical trials involving IPAP Agreements, and are the two physicians who created HHS' PMAP program.

[7] Dr. Rieber has worked on clinical trials for LBJ patients to provide cancer care for the low income and medically underserved patients of Harris County. Dr. Rieber has served as co-chair of the Harris Health System Cancer Committee and co-chair of the Oncology Pharmacy Subcommittee of the Pharmacy and Therapeutics Committee. Dr. Rieber is no longer associated with MD Andersen.

127. Manufacturers' representatives routinely visit the clinics. These representatives are deeply embedded within the clinics and frequently host lunches for employees, physicians, and resident physicians.

128. While HHS retains control over their own formularies, the formularies are decided on by physicians through a Pharmaceutical and Therapeutics Committee ("P & T Committee"). Dr. Rieber and Dr. David John Hyman, two of the physicians who originally designed the PMAP program, are voting members of the P & T Committee.

129. Subject to this practice, use of generic drugs are available and on the formulary. However, there are ordering pathways in EPIC that impede the generic drugs, increasing costs to HHS.

130. HHS program for use of replacement drugs should be structured so that the program drugs go to the pavilion/clinic where the drug was used to safeguard against the risk that participating hospitals might obtain excess stocks of drugs from which they could benefit.

131. Instead, HHS is shorting its outpatient programs, requiring each outpatient program to order, through 340B, a drug for the patient.

132. No utilization reports exist to certify that Program Drugs ("Program Drugs") are only replacing drugs provided to qualified patients. Internal audits have discovered these shortcomings, and the results of such audits reported to DOP and Medical Affairs, and yet no corrective action has taken place.

133. Program safeguards either do not exist or are ignored in the operation of HHS' bulk replacement programs.

134. As a result, HHS cannot determine if the ultimate recipients of the Program Drugs are those who are financially-needy patients who lack outpatient prescription drug coverage. Instead of using the Program Drugs for solely vulnerable, needy patients, the drugs are being diverted to HHS inpatient pharmacies.

4. How The Diversion Occurs

135. HHS is creating and submitting false claims by diverting replacement pharmaceuticals as described above and below, then billing the 340(B) program for replacements. These replacement drugs should have been purchased under another pharmacy program, such as AWC.

136. The false claim, and diversion, occurs when the free bulk replacement drug gets diverted to an inpatient/outpatient unit.

137. In the inpatient/outpatient setting, the drug that was received for free is billed to Federal or state programs.

138. HHS's method to track drug packages is antiquated and manual, and therefore this diversion occurs on a regular basis.

139. For patient-specific replacements, HHS has processes in place where the PMAP team facilitates the receipt of replacement drugs. The charge for the drug is generated in the same manner as it would be for drugs that are not replaced.

140. The PMAP team facilitates the replacement (determined by NDC code), ensures that the account meets the stated eligibility criteria, and then the account goes through the PMAP work queue to remove the drug charge and replace it with a $0 informational charge, which lets HHS staff know that the drug on the account was replaced, preventing anyone from accidentally re-adding the charge to the account.

141. In this scheme, providers, social workers, and/or drug manufacturers, who have been embedded within the department, complete the patient specific applications without informing the PMAP team. Because the PMAP team is not involved in the application, and not notified that replacement drugs have been received, the PFS processes-- for removing the charge from the account and replacing the charge with an informational charge code—do not occur.

142. Thus, the intentional failure to properly code and bill these replacement drugs permits HHS to create and submit a false claim for payment, and to be paid for the drug despite the fact that the drug was received without cost.

143. The PMAP team orders the Bulk Replacements on a monthly basis.

144. When a patient qualifies for PMAP based on particular criteria, EPIC flags the prescription for the DOP before dispensing. This process ensures that DOP will know to use replacement drugs and to not collect monies from the patients.

145. When dispensing the replacement drug, the DOP uses a code (PMAP0, used for reporting purposes only) to indicate that the product is free, rather than collecting any monies from the patient.

146. The PMAP team runs a monthly report of all drugs that were dispensed coded with PMAP0, and then audits the report to make sure all patients actually qualify for replacement drugs. By the 10th day of every month, PFS submits the final report to the manufacturer, reporting every prescription that was provided to patients who qualified for the program. This reporting is required by contract, and done so that the manufacturer can send replacement drugs for all medications provided to eligible patients.

147. The drugs are received and distributed by the DOP's Inventory section ("DOP Inventory").

148. The false billing occurs when DOP Inventory, instead of sending those bulk-replacement drugs to the intended pharmacy where the particular patient will receive the drug, instead sends the drug to an inpatient or outpatient pharmacy unrelated to the patient.

149. When the replacement drugs are received, each contains a packing slip. The packing slip clearly labels the drugs as intended for this specific patient only. See attached Exhibit 6, packing slip for two products received.

150. For patient-specific replacements diverted to inpatient/outpatient, the packing slips designate the particular patients who are to receive the drug as a replacement. See attached Exhibit 7, email regarding patient TC for a drug this patient was to receive, and the need to verify with packing slips.

151. Since the drug supposed to be provided to the patient has been diverted, the drugs actually provided to the outpatients are either billed to a payor, or charged against the indigent program.

152. The inpatient pharmacy would have to pay WAC or AWP in order to obtain these drugs. The drugs used in the outpatient prescription setting are charged by HHS at the 340(B) price.

153. DOP purchases drugs to replace the "replacement drug" at the 340B pricing in the prescription pharmacy.

154. This scheme and system continues to occur because HHS' tracking fails to analyze this problem.

155. The manufacturers are presuming, based upon audits it receives from HHS, that the drugs they send to HHS are being routed to the prescription pharmacy where the original drug was intended.

156. The manufacturers' audits do not detect this diversion because they are simply focused on ensuring the patient getting the drug qualifies for the program.

157. At the Smith Clinic and Thomas Street, prior to October 2018, the pharmacies were putting every drug package into the same supply, and using patient-specific, free drugs on patients for whom they were not intended.

158. This diversion permitted HHS to bill the replaced drugs to a payor, or put them towards an indigent program.

159. This diversion was occurring despite the agreement in each patient-specific application requiring that HHS manage these drugs and give them only to the approved patients and never to a patient with funding.

160. For example, the PMAP team replaced 24 vials of Neulasta that had been flagged as PMAP0 for LBJ's prescription pharmacy. LBJ's prescription pharmacy only received 19 of those vials through the DOP Inventory.

161. No one could explain why the diversion occurred, or where the drug replacements had gone.

162. Upon information and belief, based upon Ms. Strawn's investigation, this type of diversion occurred approximately 20% of the time. Ms. Strawn, and then HHS compliance officer Anthony Williams ("Williams"), attempted to investigate this issue with other HHS employees regarding the drug Neulasta, but, after months of attempting to investigate, were still no closer to an answer as to where missing PMAP Neulasta had been diverted. See attached, emails of December, 2018, and January, 2019, attached at Exhibit 8.

163. As recently as May 14, 2019 Williams still was investigating the whereabouts of the diverted Neulasta (see attached Exhibit 9).

164. Mr. Williams understood that Neulasta received as PMAP could not be given to an outpatient/inpatient, and that the contract with the

manufacturer required that the bulk replacement drugs only be distributed to the pharmacy where the original drug was dispensed. See email of May 15, 2019 attached at Exhibit 10.

165. Some replaced drugs were received by DOP Inventory for patient-specific replacement with a patient's initials included on the replacement product's sheet. Even though DOP knew that the existence of the initials meant the drug was patient- specific, meaning DOP had to call the PMAP hotline and get the information needed to ensure the drug went to the right patient and was compliant, DOP used that drug on anyone it wanted.

166. DOP continues this inappropriate practice because, upon information and belief, it makes drug management easier.

167. ACS ("ambulatory care services") and DOP are letting physicians complete patient-specific replacement applications without PMAP involvement, thereby increasing the risk that diversion will occur.

168. Drs. Rieber, Mims and Hyman (now deceased) had demanded that the dollar figures for purchases and replacements remain equal, meaning

that an equivalent number of purchased drugs and replacement provided drugs, are used.

169. DOP is also attempting to meet this mandate. Ms. Strawn has told the P& T Committee and the DOP that these purchases will never be equal because funded patients don't get replacement drugs, and not all manufacturers retroactively replace drugs.

170. Ms. Strawn has explained, repeatedly to Dr. Brown and others in the DOP that it is responsible for the costs of the drugs not replaced. Funded patients, due to their income, will never be eligible for replacements and cannot be calculated into the replacement figures.

171. Ms. Strawn has determined, after talking with DOP personnel, that DOP is circumventing the processes put into place by Ms. Strawn for billing, including the PMAP team and the PMAP code.

172. Ms. Strawn's processes are meant to ensure that diversion does not occur and compliant billing does occur.

173. Ms. Strawn has been involved in multiple conversations with the physicians, Dr. Brown, DOP employees, and with Mr. Norby regarding the issue

where physician/manufacturer completed the patient-specific application without PMAP's involvement, and the concern regarding diverted drugs.

174. DOP's signing up new patients without PMAP knowledge has not changed.

175. In one case, because Strawn's billing analyst did not know a drug was a replacement drug (and PMAP was not involved with the patient), a drug was billed on the claim as a $0.01, which is usually considered informational/no payment expected, with the appropriate billable units and Health Care Procedure Coding System code.

176. However, in this case, the complete circumvention of the PMAP process, upon information and belief, by a DOP supervisor, led to the replacement drug getting paid ($4,000 per month) by Medicaid for many months.

177. Ms. Strawn believes that DOP intentionally, or recklessly, diverts these drugs. Ms. Strawn holds this belief because DOP does not call Ms. Strawn's PMAP unit when the physician-driven-application drugs are received.

178. DOP acts with full knowledge that a drug received is a replacement drug, because the appropriate label is contained in each box.

179. DOP is also aware that it is supposed to notify the PMAP teams anytime a replacement drug is received. In these situations, PMAP is not, to the best of Ms. Strawn's knowledge, being notified of the drug receipt.

B. Fraudulent Use of The 340(b) Drug Discount Program

180. HHS is entitled, under Federal laws and regulations, to purchase drugs for its outpatient programs under a discount program called the 340(B) program. This discount only applies to outpatient/prescription drug purchases.

181. The fraud occurs when HHS diverts drugs purchased under the 340B program, to be used only in the outpatient program, and instead uses them for inpatients, and then re-purchases those same drugs for the outpatients under the 340B program.

182. This diversion permits HHS to pocket the difference between the inpatient drug price (under the average wholesale price (AWP) or other such purchasing programs) and the cost of the same drug under 340B.

183. The difference in prices is considerable enough, over the entire HHS family of practices, to make a significant impact on HHS' finances. This price difference is the reason that HHS is submitting false claims to the Government.

184. Pharmaceutical manufacturers who participate in the Medicaid program are required to enter into an agreement with the Secretary of HHS—called a pharmaceutical pricing agreement (PPA)—under which the manufacturer agrees to provide statutorily specified discounts on "covered outpatient drugs" purchased by government-supported facilities, known as covered entities, that are expected to serve the nation's most vulnerable patient populations[8].

185. These discounts only apply to purchases of covered outpatient drugs.[9] This agreement limits the price that manufacturers may charge certain covered entities for covered outpatient drugs.

---

[8] 42 U.S.C. § 1396r-8(a)(1), (a)(5).

[9] U.S. Government Accountability Office, Report to Committees: Drug Pricing (GAO-11-836), September 2011.

186. Covered entities (such as HHS) are allowed to dispense the discounted medication both to uninsured patients, and patients covered by Medicare or private insurance. In cases where the covered entity treats an insured patient with discounted medication on an outpatient basis, the federal government or the patient's private insurance routinely reimburses the entity for the full price of the medication and the entity is able to retain the difference between the reduced price it pays for the drug and the full price for which it is reimbursed.[10]

187. The resultant program is called the 340B Drug Pricing Program, which is administered and monitored by the Office of Pharmacy Affairs under the Health Resources and Services Administration ("HRSA"). Qualifying covered entities in the 340B Program receive a discount of up to 50% off the average wholesale price of outpatient drugs.

188. Section 340B(a)(4) of the Public Health Service Act specifies which covered entities are eligible to participate in the 340B Drug Program, and

[10] Andre Pollack, Dispute Develops Over Discount Drug Program, N.Y. Times, Feb. 13, 2013.

includes qualifying hospitals. HHS has been a participant in the 340B program participant since 1992.

189. *Program Requirements.* Section 340B requires pharmaceutical manufacturers participating in Medicaid to sell outpatient drugs at discounted prices to health care organizations that care for many uninsured and low-income patients. These organizations include community health centers, critical access hospitals ("CAHs"), rural referral centers ("RRCs"), and public and nonprofit disproportionate share hospitals ("DSH") that serve low-income and indigent populations.

190. To purchase drugs at the 340B price,[11] covered entities must meet the following ongoing requirements:

1. Keep 340B DHHS' Office of Pharmacy Affairs Information System ("OPAIS") information accurate (as to information regarding outpatient facilities and contract pharmacies) and up to date.

[11] Under section 340B(a)(1) of the Public Health Service Act, manufacturers of covered outpatient drugs that participate in the 340B Drug Pricing Program (340B Program) must offer all covered outpatient drugs at no more than the 340B ceiling price to a covered entity listed on HRSA's public 340B database if such drug is made available to any other purchaser at any price.

2. Recertify eligibility every year.

3. Prevent diversion to ineligible patients. Covered entities must not resell or otherwise transfer 340B drugs to ineligible patients.

4. Duplicate Discount Prohibition: Manufacturers are prohibited from providing a discounted 340B price and a Medicaid drug rebate for the same drug. Covered entities must accurately report how they bill Medicaid fee-for-service drugs on the Medicaid Exclusion File, as mandated by 42 USC 256b(a)(5)(A)(I).

5. Prepare for program audits.

191. Prescription data and documentation available in HHS' own 340B information systems can verify eligibility. Within the information systems, the precise date, location and circumstances around 340B prescriptions are validated.

192. Drug diversion in the 340B program is defined as a 340B drug being provided to an individual who is not an eligible outpatient of that entity. Drug diversion also occurs when a drug is dispensed in an area of a larger

facility that is not eligible for participation in the 340B program (e.g., an inpatient service or a non-covered clinic).

193. HRSA defines drug diversion include (a) dispensing 340B drugs at ineligible sites; (b) not monitoring and correcting inventory; (c) dispensing 340B drugs written by ineligible providers; (d) dispensing 340B drugs to non-eligible patients at a contract or onsite pharmacy.

194. HRSA does not have statistics to illustrate the cost of drug diversion within the 340B Program, but roughly estimates that 10% of the drugs dispensed get diverted, which would equal a cost of $7.1 million annually.

195. HRSA performs audits each year, looking for common areas of noncompliance, including drug diversion, duplicate discounts, and ineligible sites/providers. In October 2014, there were a total of 28,306 sites registered with the 340B Program. With more sites qualifying for the program annually, HRSA is challenged with enforcing 340B compliance.

196. HRSA is aware of this concern, stating on its website that

> Noncompliance to 340B program impacts patients' bottom line because the more diversion that occurs, the more drug manufacturers increase prices for both public and private insurers, leading to an increase in rates and charges to patients. If HRSA were able to enforce 340B regulations and audit all hospitals on a continual basis, there would be fewer cases surrounding duplicate discounting, drug diversion, and ineligible site/providers.

197. In 2018, HRSA audited at least 199 programs, and came to findings such as:

> • Baptist Hospitals of Southeast Texas dba Baptist Beaumont Hospital DSH450346 TX. Diversion - 340B drugs dispensed at contract pharmacies for prescriptions written at ineligible sites. Remedy: Repayment to manufacturers.
>
> • Billings Clinic, MT. DSH270004. Diversion – 340B drugs dispensed to inpatients. Repayment to manufacturers pending.
>
> • Alcona Citizens for Health, Inc., MI. CH051980. Diversion - 340B drugs dispensed at entity for prescriptions written at ineligible sites. Repayment to manufacturers; CAP implemented. Audit closure date: June 25, 2019.

- Baystate Franklin Medical Center, MA. DSH220016 Diversion - 340B drugs dispensed at contract pharmacies for prescriptions written at ineligible sites. Repayment to manufacturers; CAP approved.

198. In 2018, of the 101 covered entities undergoing audits, 28 of them were cited for diversion. In most of these cases, diversion occurred when the 340B drugs were dispensed at contract pharmacies for prescriptions written at ineligible sites or that were not supported by a medical record; given to inpatients; or improperly accumulated.

199. Diversion identified during a HRSA audit requires covered entities to submit repayments to manufacturers, develop and implement a Corrective Action Plan (CAP) and participate in a follow-up audit.

200. In February 2016, CMS required states to have established by April 1, 2017 reimbursement policies specific to retail 340B Medicaid FFS drugs and to pay for such drugs based on their actual acquisition cost (AAC).

201. CMS required that reimbursement for retail 340B FFS drugs cannot exceed the 340B ceiling price. CMS also said that states may pay higher

dispensing fees for retail 340B FFS drugs to accommodate 340B pharmacies' increased dispensing costs.

202. Once CMS codified the prices in 42 C.F.R. §10.10, the price ceilings were set as follows:

> A manufacturer is required to calculate the 340B ceiling price for each covered outpatient drug, by National Drug Code (NDC) on a quarterly basis.
>
> > (a) Calculation of 340B ceiling price. The 340B ceiling price for a covered outpatient drug is equal to the Average Manufacturer Price (AMP) from the preceding calendar quarter for the smallest unit of measure minus the Unit Rebate Amount (URA) and will be calculated using six decimal places. HRSA will publish the 340B ceiling price rounded to two decimal places.
> >
> > (b) Exception. When the ceiling price calculation in paragraph (a) of this section results in an amount less than $0.01 the ceiling price will be $0.01.
> >
> > (c) New drug price estimation. A manufacturer must estimate the 340B ceiling price for a new covered outpatient drug as of the date the drug is first available for sale. That estimation should be calculated as wholesale acquisition cost minus the appropriate rebate percentage until an AMP is available, which should occur no later than the 4th quarter that the drug is available for sale. Manufacturers are required to calculate the actual 340B ceiling price as described in paragraph (a) of this section and offer to refund or credit the covered entity the difference between the estimated 340B ceiling price and the actual 340B ceiling price within 120 days of the determination by the manufacturer that an overcharge occurred.

203. HHS continues to recoup larger amounts of monies from its diversion of 340B drugs into settings where the use of 340B drugs is not permitted.

C. INTENTIONAL RECEIPT OF OVERPAYMENTS FOR VACCINES

204. Defendant, in the clinics and its hospitals, administers immunizations (also called vaccines) to children and adults. Vaccines are, for the most part, administered via injection into a large muscle, i.e., by intramuscular injection ("IM").

205. Defendant is permitted to charge, in most circumstances,[12] for two parts of the vaccine– the actual medicines, and the administration of the medicine.

206. In Defendant's clinics and hospitals, most vaccines are administered by registered nurses. Vaccines may also be administered by licensed practical nurses and pharmacists.

[12] Children who economically qualify receive the vaccine medicine, but not the administration, free under the CDC's "Vaccines for Kids" ("VFK") program.

207. In order to administer a vaccine, the nurse would be required to obtain an order from a physician or nurse practitioner. After the order was obtained and the patient identified, the nurse would obtain the vaccine medicine and administer the vaccine medicine to the properly identified patient.

208. As HHS, prior to 2016, in order to document the administration of the medicine and bill for the vaccine medicine and the administration, the entered order for the medicine would generate a charge, then the nurse would manually enter an administration code for the act of administering the vaccine, and a nurse electronically signing the Medication Administration Record ("MAR") for the particular patient, would generate a charge.

209. In mid-2016, Defendant's IT department, in conjunction with its clinic directors, decide to streamline the charging of vaccines, potentially to avoid a situation where one of the three entries noted above would be mistakenly missed, and charges would not occur.

210. Ms. Strawn was excluded from conversations regarding how best to resolve the problem of insuring that nurses were not required to take too many steps in the electronic record after providing a vaccine.

210. The solution "created" by IT and the clinical directors, was to develop the "CAM" (clinic administered medication) project. One hundred and fifty (150) outpatient drugs and biologics (which includes vaccines) were approved to be administered in clinics, and an IT linkage was created between the clinical component and the charge component of vaccines and immunizations.

212. The point of these actions was to merge the medication and administration charge into one charge, so that nurses would no longer need to manually enter the administration charge. Instead, the IT department plan was that once the nurse documents on the MAR that the medication–in this case, the vaccine–was administered, the charges (medicine and administration) would be processed automatically, as a "charge on administration" code.

213. However, the effectuation of this "solution" depended upon the clinic staff being educated on the "new" means of billing for vaccines.

214. HHS decided to start this program, as it relates to vaccines, with the pediatric population first, and then move to the adult population.

215. Beginning in early 2017, when the program should have begun, HHS failed to educate its staff on this new program.

216. As a result, every time a vaccine order was entered, the medicine and administration charge was submitted as two separate charges—the charge on administration code, and either another medicine code or another administration code, or both.

217. In addition, at least 230 departments in EPIC were not converted to "charge on administration" (via the MAR entry), and instead left at "charge on dispense," requiring a separate charge entry for administration.

218. Uneducated nurses continued to submit the administration charge, either via a manual entry or through electronically signing the MAR, or both.

219. For childhood vaccines, the majority of the patients are indigent but have Medicaid (Texas Health Steps–THSteps or EPSDT) or grant funding

(Title V Maternal and Child Health Services Block Grant). Most childhood vaccine medicines are free, supplied by the VFK program.

220. Between adults and children, approximately 60% of the persons receiving vaccines are indigent; 20% are on Medicaid; 9.5% are on Medicare; and 10% are on private insurance.

221. As a result of this intentional, or reckless, failure since 2016 to ensure that charges are properly programmed into, and then entered into, the system, nurses are submitting charges at least twice– once by electronically signing the MAR, and a second time by manually entering an administration code.

222. As a result, Medicare and Medicaid are double billed for administration of vaccines.

223. Large amounts of indigent patients, for whom HHS' costs are reported as unpaid, and therefore subject to the HHS' Disproportionate Share payments ("DSH"), are receiving vaccines and having their costs coded as unreimbursed at double to triple the rate that the vaccines are actually administered.

224. On August 2, 2017, Ms. Strawn notified Jose Mathews ("Mathews"), and others, that at least 600 duplicate charges per month were being submitted, as a result of the ability to enter a manual charge still existing in the computer system.

225. By August 17, 2017, Ms. Strawn had estimated that these errors were resulting in an average of 1,000 duplicate charges per month. The number of duplicate charges dramatically increases during flu season.

226. Ms. Strawn and her staff had no way to resolve this problem, as they had no control over IT or ACS, the actual owner of the workflow, and no edit possible for charges routing to two different claims, the 1500 (in most situations sent directly to Baylor or University of Texas for billing[13]) and the UB-04 (billed by HHS).

227. As of August 21, 2017, Ms. Strawn notified HHS management about this issue and others, stating that she would not sign off on new system builds until the original issues were resolved. (See emails attached as Exhibit 11).

[13] Physicians, residents, and nurses are sometimes Baylor or UT employees, so Baylor or UT bill for their services.

228. By March 2018, the problem related to double billing for vaccine administration was still not resolved. On March 22, 2018, Ms. Strawn notified Norby that, after meeting with IT and Compliance, all parties agreed that "the system is not set up as designed and that the current build puts [the health system] at risk for inappropriate charging/ billing." (See, Exhibit 12).

229. In March 2018, the only means Ms. Strawn had to deal with these overcharges was by "tackling highest volume errors as a priority..."; "... make sure all visible inappropriate payments are refunded via payor checks and spreadsheets since rebills will result in recoups of all monies paid (even if some charges are appropriately charged/ billed)."

230. PFS, Ms. Strawn's department, has no visibility for provider payments made to Baylor or UT and HHS. Therefore, the need for refund would not be identified or initiated in situations where charges went out from either Baylor, UT or HHS.

231. The highest volume errors were occurring in the flu vaccine, and this vaccine was the one tackled by Ms. Strawn and her employees. Despite

numerous meetings between August, 2017, and June, 2018, no resolution of the problem had occurred.

232. By June 21, 2018, IT was about to permit testing of its new program for vaccine administration to occur, yet would not permit clinicians to access the new program to test its effectiveness. (See email of June 21, 2018 attached as Exhibit 13).

233. On November 2, 2018, IT coordinator and the PFS Pharmacy Business Office Manager stated that . . . . "[e]ven if these IMMS were to be rolled out, many of the same issues will continue until the following are in Production.... Remaining Pedi IMM records we fixed back in July; Adult IMM records (yet to be created); Users stop posting manual vaccine and vaccine admin charges; charge handler adult routing rules..." (See, Exhibit 14).

234. On November 21, 2018, Strawn advised her supervisor, Michael Norby, that they had "created a presentation that compiles the issues in a condensed manner, provides associated timelines, including recommendations." (See, Exhibit 15).

235. Yet, despite many years of discussions and inaction, these charges continued to be processed.

236. For instance, on December 12, 2018, patient AGA[14] received the adult pneumonia vaccine and the flu vaccine. Defendant charged Medicare Managed Care twice for the pneumonia vaccine as a combined charge (vaccine and administration) of $128.00, and then twice for the administration of the pneumonia vaccine, at $14.85.

237. For instance, on December 12, 2018, patient CCM received the TDAP vaccine ("Tetanus, Diptheria, and Attenuated Pertussis"). Defendant charged Medicaid Managed Care twice for the vaccine as a combined charge of $67.00, and twice for the administration of the TDAP vaccine, at $14.85.

238. For instance, on December 12, 2018, patient MC received the TDAP vaccine. Defendant charged Medicaid twice for the vaccine as a combined charge of $67.00, and twice for the administration of the TDAP vaccine, at $14.85.

[14] Patient names and elsewhere herein have been withheld or redacted to protect private health information. Such information will be provided to defendant upon request

239. By HHS' own admission, these duplicate charges were occurring due to inconsistent or multiple work flows, encounters not being closed on a timely basis, and/or outpatient vaccine administrations being documented on the MAR and charged separately.

240. Despite full knowledge of its overcharging, Defendant has failed to rectify this situation for several years.

241. Defendants are also posting double charges for indigent patients, such as SP, on the Harris County Hospital District Plan, who was posted twice for both the flu vaccine and the administration of the flu vaccine.

242. These charges for indigent patients are absorbed in HHS' cost reports, filed with the Federal and State Governments, and are one of the items that form the basis of the DSH Payments made to HHS each year, which account for a significant share of HHS' annual income.

243. These false billings result in false claims to the United States and the State of Texas.

D. BILLING FOR NEWBORN SERVICES NOT PROVIDED

244. HHS, mainly at its LBJ Hospital site, bills for newborns as if they are all being housed in high acuity beds when in fact most of them are in the same room as their mothers.

245. As a result, HHS is falsely billing for these high acuity beds when normal newborn care is being provided.

246. These false submissions result in inappropriate cost outlier payments by the Medicaid system, and results in excessive "unpaid care" for the indigent patient base, which negatively impacts and inflates HHS' DSH payments.

247. As early as December, 2016, HHS had been notified by the State Medicaid program that its charges for newborn care were excessively high and likely higher than the state average. In particular, the Medicaid program saw higher than expected billing, mostly occurring at LBJ, for normal weight newborns.

248. After an investigation, Ms. Strawn determined that, at LBJ, the newborns were "rooming in" with the mothers– in a bassinette in the room

with the mother–but for billing code purposes, were assigned the highest level acuity "bed", revenue code 174–Level IV.

249. On December 19, 2016, Ms. Strawn and her team audited the LBH units, determined the cause of the problems, and reached out to the nurses and staff on the units–2A and 2H–to update them on the cause of the problems.

250. At this point, and with HHS' executive leadership's and Compliance's support, Ms. Strawn had no concerns that the problem could be remedied. Ms Strawn also, at this point, had no concerns about fraud because, among other reasons, LBJ and HHS were paid under a DRG, regardless of bed used, and only received additional payments if the newborn needed extended care, under an outlier program, which rarely occurred.

251. The other issue raised in this audit, and investigation, was whether the level of care provided for all newborn patients was being monitored and adjusted daily. The level of care noted, and therefore charged, must be based on the severity of the patient's illness and the level of care being provided.

252. For example, there are four levels of care provided to newborns, graded as Newborn Levels I through IV, which must be assessed each day. These levels are unrelated to the neonatal intensive care unit ("NICU") certification or the physicians' inpatient visit charges (normal, intermediate, and critically ill).

> Newborn Level I: this level reflects routine care of apparently normal full- term or preterm neonates (considered to be newborn nursery).
>
> Newborn Level II: the level reflects low birth-weight neonates who are not sick but require frequent feeding and neonates who require more hours of nursing than do normal neonates (considered to be continuing care).
>
> Newborn Level III: This level reflects sick neonates who do not require intensive care, but requires six to 12 hours of nursing each day (considered to be intermediate care).
>
> Newborn Level IV: this level reflects newborns who need constant nursing and continuous cardiopulmonary and other support for severely ill infants (considered to be intensive care).

253. At the time of this audit and finding, after meeting with HHS' executive leadership and providing departmental training, it was agreed that each night, at midnight, a Midnight Census Audit would be performed on each unit, including 2A and 2H, which should insure that

the accurate level of care for each newborn, and all patients across the organization, is correctly inputted into the system.

254. Despite the required updating of the system necessary to implement this program, and the training that was performed to educate the staff, the necessary nightly audits--meant to reconcile the patients' care to the level being charged billed--never occurred or were not sustained long-term.

255. The workflow meant to manage the appropriate room charging required that the nurses on the units in question agree to participate and take ownership of the daily task. That has still not occurred.

256. Multiple levels of HHS' administration have been notified that, despite education given to the nurses on the proper way of entering the data into EPIC, the nurses refuse to participate and fix the problem.

257. Nursing continues to insist that only physicians can make the appropriate level-of-care determinations, even though they have been instructed to do so and informed that it is HHS, and not the physicians, who are at risk for inappropriate overpayments.

258. Efforts to educate the physicians and hold the physicians accountable resulted in the physicians requesting that Level II and Level III be combined, leaving only Levels I, III, and IV. This request was made in order to have the hospital room charge levels equal to the providers' inpatient visit codes (newborn, intermediate, and critically ill).

259. For instance, patient FA, born on March 3, 2018, was transferred to the NICU for closer monitoring. Physician notes specifically state that the patient was "transferred to level 3..." But charges entered by the nurse for the three day admission show that the patient's stay was billed as level 4.

260. For instance, Patient SS was admitted for one day, and discharged to home, yet billed as a level 4. Any newborn patient only admitted for one day and discharged alive could not have logically had the degree of health issues necessary for a level 4 stay.

261. For instance, Patient LO had a one day stay, and was billed for level 4. During LO's birth, a NICU staff member was present due to concerns related to her mother's prenatal health, which fortunately did not result in the need for level 4 care. Despite this outcome, Patient LO's stay was billed as Level 4.

262. A large number of HHS' newborns are put into level II, III, and/or IV when they do not qualify. This was brought to HHS', attention in December 2016 by HHSC, when the health plan told HHS that it billed for a higher level of care 60-70% more often than its peers.

263. Based on these findings and the fact that HHS agreed there was a problem, systems were updated and education was provided and commitments were made.

264. In February 2019, when HHS received an audit from CHC regarding a $34,000 overpayment, Ms. Strawn realized that processes had not changed because HHS had charged, for this one patient, higher than medically necessary room charges for 81 of the patient's 163 days.

265. In this one situation, a newborn patient stayed for an extended period of time. Most days were billed as Level 4 despite the fact that many days, the level of service provided was at a Level 3 or lower.

266. Ms. Strawn audited this patient's chart in response to a request for information from CHC, and found that, if the room charges were billed based on medical necessity, HHS would have been paid $34,000 less than it was paid.

267. The table below shows what the room charges should have been (per Ms. Strawn's medical necessity audit): $285,013.00.

Level of Care	Number of Days	Charge Rage	Total
LOC IV	74	$2,527.00	$186,998.00
LOC III	70	$1,236.00	$86,520.00
LOC II	19	$605.00	$11,495.00

This shows (line one and two) what the room charges actually were:

Copied From Epic

Rev Code	Description	Qty	Total Amt
173	NURSERY - NEWBORN - LEVEL III	8	9,888.00
174	NURSERY - NEWBORN - LEVEL IV	155	391,685.00
250	PHARMACY – GENERAL	22,374	55,027.64
255	PHARMACY – DRUGS INCIDENT TO RADIOLOGY	5	6.04
258	PHARMACY – IV SOLUTIONS	485	4,504.26
272	MEDICAL/SURGICAL SUPPLIES AND DEVICES – STERILE SUPPLY	3	249.30
300	LABORATORY - GENERAL	1,301	117,076.00
310	LABORATORY PATHOLOGICAL – GENERAL	4	758.00
320	RADIOLOGY – DIAGNOSTIC – GENERAL	25	5,616.00
324	RADIOLOGY – DIAGNOSTIC – CHEST X-RAY	86	21,653.00
360	OPERATING ROOM SERVICES - GENERAL	12	44,298.00
361	OPERATING ROOM SERVICES – MINOR SURGERY	267	1,330.00
370	ANESTHESIA – GENERAL	2	3,993.00
382	BLOOD – WHOLE BLOOD	16	2,496.00
383	BLOOD – PLASMA	4	700.00
384	BLOOD – PLATELETS	5	3,745.00
387	BLOOD – OTHER DERIVATIVES (CRYOPRECIPITATES)	1	63.00
389	BLOOD – OTHER BLOOD	1	156.00
390	BLOOD STORAGE AND PROCESSING – GENERAL	27	8,914.00
391	BLOOD STORAGE AND PROCESSING – BLOOD ADMINISTRATION	25	9,425.00
402	OTHER IMAGING SERVICES – ULTRASOUND	10	6,621.00
410	RESPIRATORY SERVICES – GENERAL	1,871	81,306.00
420	PHYSICAL THERAPY – GENERAL	47	6,645.00
424	PHYSICAL THERAPY – EVALUATION OR REEVALUATION	3	535.00
440	SPEECH-LANGUAGE PATHOLOGY – GENERAL	7	2,870.00
444	SPEECH-LANGUAGE PATHOLOGY – EVALUATION OR REEVALUATION	2	1,102.00
449	SPEECH-LANGUAGE PATHOLOGY – OTHER SPEECH-LANGUAGE PATHOLOGY	2	0.02
469	PULMONARY FUNCTION – OTHER PULMONARY FUNCTION	1	161.00
483	CARDIOLOGY – ECHOCARDIOLOGY	15	11,885.00
611	MAGNETIC RESONANCE TECHNOLOGY (MRT) - MRI BRAIN (INCLUDING BRAIN STEM)	1	5,563.00
636	DRUGS REQUIRING SPECIFIC IDENTIFICATION - DRUGS REQUIRING DETAILED CODING	16,852	36,918.95
740	EEG (ELECTROENCEPHALOGRAM) - GENERAL	1	285.00
921	OTHER DIAGNOSTIC SERVICES - PERIPHERAL VASCULAR LAB	1	1,300.00
999	PATIENT CONVENIENCE ITEMS - OTHER PATIENT CONVENIENCE ITEMS	5	0.00
Total		**43,624**	**836,775.21**

Patient	[redacted]				
Dates of Service	12/02/2017 - 05/14/2018				
Fiscal Year	**2018**				
Tefra Rate for DOS	**0.55**				
FY Universal Mean	$6,505.52	TMHP Letter			
FY SDA	$5,592.12	DRG Tables			
DRG relative weight	32.1973	DRG Tables			
A)	11.14 X FY U.M.	$72,471.49			
			(use lesser of A and B) >>	$62,296.22	A/B
B)	11.14 X FY SDA	$62,296.22			
C)	1.5 X DRG Relative Weight	48.29595			
	X FY SDA	$270,076.75	A/B)>>	$270,076.75	Cost Threshold
D)	CHARGES	$834,193.21			
	X Tefra rate for DOS	0.55	(per Cost Settlement Report)		
E)	calculated cost	$458,806.27			
	minus cost threshold	$270,076.75	(from comparison A/B & C)		
F)	cost outlier	$188,729.52			
	X 0.60	0.6			
G)	Expected Cost Outlier	$101,913.94			
	Expected DRG payment	$180,051.17			
	Total Payment Expect.	**$281,965.10**			

Patient	[redacted]				
Dates of Service	12/02/2017 - 05/14/2018				
Fiscal Year	**2018**				
Tefra Rate for DOS	**0.55**				
FY Universal Mean	$6,505.52	TMHP Letter			
FY SDA	$5,592.12	DRG Tables			
DRG relative weight	32.1973	DRG Tables			
A)	11.14 X FY U.M.	$72,471.49			
			(use lesser of A and B) >>	$62,296.22	A/B
B)	11.14 X FY SDA	$62,296.22			
C)	1.5 X DRG Relative Weight	48.29595			
	X FY SDA	$270,076.75	A/B)>>	$270,076.75	Cost Threshold
D)	CHARGES	$717,633.21			
	X Tefra rate for DOS	0.55	(per Cost Settlement Report)		
E)	calculated cost	$394,698.27			
	minus cost threshold	$270,076.75	(from comparison A/B & C)		
F)	cost outlier	$124,621.52			
	X 0.60	0.6			
G)	Expected Cost Outlier	$67,295.62			
	Expected DRG payment	$180,051.17			
	Total Payment Expect.	**$247,346.78**			

268. Situations like those described continue to occur on a daily basis because HHS refuses to act on and rectify this situation.

269. As a result of these actions, and the refusal to rectify the situation, HHS is submitting false claims to Medicaid and Medicare, and being paid under these false claims.

III. DAMAGES SOUGHT

270. The measure of damages the United States and the State of Texas are entitled to recover under the FCA and the Texas Medicaid Fraud Prevention Act, Tex. H.R. Code § 36.001 et seq, and §32.039 et seq., is the amount of money the United States and State of Texas paid out by reason of the false claims.

271. The United States is allowed to recover three times the amount of its damages, 31 U.S.C. § 3729(a), to ensure that it receives the Government complete indemnity for the injuries done it.

272. The State of Texas is allowed to recover two times the amount of its damages, Tex. H. R. Code § 36.052 and §32.039(c).

273. Damages in this case are the amounts paid to Defendants by Medicare and Medicaid for HHS' improper and unlawful claim submissions.

IV. CAUSES OF ACTIONS

COUNT ONE

THE FCA: 31 U.S.C. § 3729(a)(1)(A)

274. All of the allegations set forth in paragraphs 1 through 273 are incorporated herein by reference as if fully set forth at length.

275. The FCA, 31 U.S.C. § 3729(a)(1)(A) makes "knowingly" presenting, or causing to be presented, to the United States, any false or fraudulent claim for payment or approval, a violation of federal law for which the United States may recover three times the amount of the damages the government sustains and a civil monetary penalty of between $10,781 and $21,563.00 per claim.

276. By the actions as described above, Defendants have submitted false claims to the United States, by and through its Medicare and Medicaid programs.

277. Defendant's actions were material to the Government's payment decisions.

278. As a result of Defendants' actions, the Government has been damaged.

COUNT TWO

THE FCA: 31 U.S.C. § 3729(a)(1)(B)

279. All of the allegations set forth in paragraphs 1 through 278 are incorporated herein by reference as if fully set forth at length.

280. The FCA, 31 U.S.C. § 3729(a)(1)(B) makes "knowingly" making, using, or causing to be used or made, a false record or statement material to a false or fraudulent claim, a violation of federal law for which the United States may recover three times the amount of the damages the Government sustains and a civil monetary penalty of between $10,781.00 and $21,563.00 per claim.

281. By the actions as described above, Defendants have made, used, or caused to be made or used, false statements material to a false claims to the United States, by and through the Medicare and Medicaid programs.

282. Defendants' actions were material to the Government's payment decisions.

283. As a result of Defendants' actions, the Government has been damaged.

COUNT IV
VIOLATIONS OF THE TEXAS HUMAN RESOURCES CODE
TEX.H.R. §32.039; AND §36.001 ET SEQ.

284. All of the allegations set forth in paragraphs 1 through 283 are incorporated herein by reference as if fully set forth at length.

285. The Texas Human Resources Code, §32.039 et seq., states that a person commits a violation of the Code if the person presents or causes to be presented to the department a claim that contains a statement or representation the person knows or should know to be false.

286. The Texas Human Resources Code, §36.001 et seq, states that a person commits an unlawful act if the person (1) knowingly makes or causes to be made a false statement or misrepresentation of a material fact to permit a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized; or (2) knowingly conceals or fails to disclose information that permits a person to receive a benefit or payment under

the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized; or (3) knowingly makes, causes to be made, induces, or seeks to induce the making of a false statement or misrepresentation of material fact concerning information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid; or (4) conspires to commit a violation of the law; has committed an unlawful act.

287. If a person has committed such an unlawful act under the Texas Human Resources Code §32.039, the State of Texas may institute an action against the person to recover from the person (1) the amount paid, if any, as a result of the violation and interest on that amount determined at the rate provided by law for legal judgments and accruing from the date on which the payment was made; and (2) payment of an administrative penalty of an amount not to exceed twice the amount paid, if any, as a result of the violation, plus an amount: (A) not less than $5,000 or more than $15,000 for each violation that results in injury to an elderly person, as defined by Section 48.002(1) of the Texas Human Resources Code, a disabled person, as defined by Section 48.002(8)(A) of the Texas Human Resources Code, or a person younger than 18 years of

age; or (B) not more than $10,000 for each violation that does not result in injury to a person described by Paragraph (A).

288. If a person has committed such an unlawful act under the Texas Human Resources Code §36.001 et seq., the State of Texas may institute an action against the person to recover from the person (1) the amount of any payment or the value of any monetary or in-kind benefit provided under the Medicaid program, directly or indirectly, as a result of the unlawful act, including any payment made to a third party; (2) interest on the amount of the payment or the value of the benefit at the prejudgment interest rate in effect on the day the payment or benefit was received or paid, for the period from the date the benefit was received or paid to the date that the state recovers the amount of the payment or value of the benefit; (3) a civil penalty of: (a) not less than $5,500 or the minimum amount imposed as provided by 31 U.S.C. § 3729(a), if that amount exceeds $5,500, and not more than $15,000, or the maximum amount imposed as provided by 31 U.S.C. § 3729(a), if that amount exceeds $15,000, for each unlawful act committed by the person that results in injury to an elderly person, as defined by Section 48.002(a)(1), a person with a disability, as defined by Section 48.002(a)(8)(A), or a person

younger than 18 years of age; or (b) not less than $5,500 or the minimum amount imposed as provided by 31 U.S.C. § 3729(a), if that amount exceeds $5,500, and not more than $11,000 or the maximum amount imposed as provided by 31 U.S.C. § 3729(a), if that amount exceeds $11,000, for each unlawful act committed by the person that does not result in injury to a person described above; and (4) two times the amount of the payment or the value of the benefit described above.

289. By the actions as described above, Defendants have presented, or caused to be presented, and made, used, or caused to be made or used, false statements to get a false claims paid or approved; to the State of Texas, by and through the Medicaid programs.

290. Defendant's actions were material to the State of Texas' payment decisions.

291. As a result of Defendant's actions, the State of Texas has been damaged.

V. RELIEF REQUESTED

292. Relator Tina Strawn, R.N., requests the following relief be imposed against Defendant:

(a) That the United States be awarded three times the amount of damages which it sustained because of the acts of Defendant pursuant to §3729(a)(1)(A) and (B) of the FCA;

(b) That Defendant be held liable for civil penalties of up to $21,563.00, but not less than $10,781.00 (as adjusted pursuant to §3729 of the FCA and the Civil Penalties Act), to the United States for each and every act in violation of the FCA;

(c) that the State of Texas be awarded two times its actual damages, as provided by Tex. H. R. Code §32.039 et seq. and §36.001 et seq.;

(d) that Defendant be held liable for civil penalties as provided by the Texas Human Resource Code for each and every act in violation of the Code;

(e) that this Court award such interest as is available pursuant to the FCA and the Texas Human Resources Code;

(f) That in the event the United States intervenes in this action and takes over its prosecution, the Relator be awarded an amount for bringing this action on behalf of the United States of at least 15% but not more than 25% of the proceeds paid to the United States resulting from the trial or settlement of the claim, pursuant to §3730(d)(1) of the FCA;

(g) That in the event the United States does not intervene in this action, the Relator be awarded an amount for bringing this action for the United States of at least 25% but not more than 30% of the proceeds paid to the United States resulting from the trial or settlement of the claim, pursuant to §3730(d)(2) of the FCA;

(h) That in the event the State of Texas recovers funds as a result of this Complaint, the Relator be awarded at least 15% but not more than 30% of any recovery as a result of claims pursuant to Tex. Human Resources Code §36.001 et seq; and at least 5% of any recovery as a result of claims pursuant to Tex. Human Resources §32.039 et seq.

(i) That this Court award reasonable attorneys' fees, costs and expenses to the Relator, which were necessarily incurred in bringing and

prosecuting this case, pursuant to §3730(d)(1) or (2) of the FCA; and Tex. Human Resources Code §36.110; and

(j) That this Court award such other relief as it deems just, necessary and fair.

Relator requests a trial by jury of all issues so triable.

RESPECTFULLY SUBMITTED,

/s/ Robert E. Goodman, Jr.

KILGORE & KILGORE, PLLC
By: Robert E. Goodman, Jr.
Texas Bar No. 08158100
U.S. District Court, SD of Texas, Bar No. 278353
Kilgore Law Center
3109 Carlisle Street
Dallas, Texas 75204
(214) 969-9099
Email: reg@kilgorelaw.com

BEGELMAN & ORLOW, P.C.
By: Marc M. Orlow *admitted PHV*
Ross Begelman *admitted PHV*
411 Route 70 East, Suite 245
Cherry Hill, New Jersey 08034
(856) 428-6020
Email: marc.orlow@begelmanorlow.com
Attorneys for Relator

February 11, 2021